REMARKS

I. Formal Matters

Applicants hereby enclose a certified copy of the priority document EP97203607.3.

II. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Office has rejected claim 15 because "costimulatory molecules" lacked antecedent basis due to dependence on claim 13.. Applicants inadvertently referenced claim 13 instead of claim 14. Claim 15 has been amended to reflect the correction of this typographical error.

III. Rejections Under 35 U.S.C. § 112, First Paragraph

A. The Office has rejected claim 13 as containing subject matter which was not described in the specification in such a way as to as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time of filing. The Office contends that "there is no support in the specification or the claims as originally filed for the recitation of a composition comprising the monoclonal antibody of any one of claim 1-3 , 'wherein the autoantigen is a heat shock protein that stimulates type 2 cytokine producing regulatory T-cells.'" (Office Action at page 2.)

Applicants respectfully traverse this rejection. Applicants refer the Office to page 3, line 25, to page 4 line 2, in which the discussion refers to previous treatments with autoantigens and fragments thereof. It goes on to state that the present invention combines the administration of autoantigens with modulation of the cytokine microenvironment to enhance antigen-specific therapy. At page 5, lines 13-17, the Summary of the Invention again refers to the combination of treatment with an autoantigen and an anti-IL-12R beta-2 chain antibody. Original claim 4 claims the autoantigen or peptide fragments thereof in combination with the monoclonal antibody of

claims 1-3 and original claim 5 indicates that the autoantigen can be, among other proteins, "a heat shock protein".

Therefore, it is not understood why the Office alleges that there is no written description for claim 13. In view of the clear disclosure in the specification, Applicants assert that there is no new matter in claim 13 and the rejection should be withdrawn.

IV. Rejections Under 35 U.S.C. § 102

Claims1-3 and 16 are rejected as being anticipated by EP 0759466 A2. The Office alleges that the monoclonal antibodies disclosed in the '466 application anticipate the antibodies of the present invention.

Applicants respectfully traverse this rejection. The '466 application discloses antibodies which block the binding of IL-12. The present invention claims antibodies which block the dimerization of the IL-12R beta 1 and beta 2 chains and prevent Beta 2 chain-mediated phosphorylation of STAT4. There is no mention in the '466 application of the ability of these antibodies to block dimerization. Moreover, it is more likely that the epitope that recognizes IL-12 is different from the epitope that dimerizes with the beta 1 chain of IL-12R. Thus, Applicants assert that the antibodies disclosed in the '466 application do not anticipate the claimed invention of claim 1-3 or 16 and the rejection should be withdrawn.

V. Rejections Under 35 U.S.C. § 103

Claims 1-3, 14 and 18 are rejected as unpatentable over the '466 application in view of Janeway et al.

In view of the discussion in section IV above, Applicants assert that the primary reference does not disclose antibodies that "prevent IL-12R beta2 chain-mediated STAT4

phosphorylation" or "dimerization to the IL12R beta1 chain" as required by the claims. Therefore, this rejection should be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants submit that the application is condition for allowance and request a timely notice.

Respectfully Submitted,

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Marked Version of Amended Claim:

15. (Amended) The composition of claim 14 [13], wherein the costimulatory molecule bound by the second monoclonal antibody is CD40, CD40L, CD80, or CD86.